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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/719,602

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Samantha K. Holme

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

04/01/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/719,602	<b>Applicant(s)</b> HOLME ET AL.	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-30, 33, 35, 36, 39, 40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16, 18, 19, 26-28 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 20-25, 29, 30, 33, 35, 39, 40 and 42-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Applicants' arguments, filed December 1, 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)**

1) Claims 20-24, 29 and 30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (WO 01/39606) in view of Sagel et al (6,582,708). The rejection is maintained. The rejection is maintained in regards to claims 20-23, 29 and 30 and further applied to claims 1-8, 33, 39, 40, 42 and 43. The rejection is withdrawn in regards to claim 24.

#### **Applicant's Arguments**

Applicant argues there is no teaching or suggestion in Day of the problems associated with placing polyphosphate in the gum base, such as the base impeding the releases of the polyphosphate to perform a stain removing function. Further Day does

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not disclose any other stain removing agent may be incorporated into the coating.

Applicant also argues the citation of Sagel does not provide additional teaching or motivation for one of ordinary skill in the art to materially change the compositions of the primary reference to arrive at the claimed invention. This argument is not persuasive.

Examiner's Response

Although Day does not disclose the problems associated with adding polyphosphate to the gum base, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144, IV. Further Day does teach encapsulating or adding the polyphosphate to the coating of the disclosed chewing gum. This meets the limitation of the stain removing component not being materially bound to the gum base. Day et al. further discloses whitening agents and Sagel et al. discloses that the stability of whitening agents is improved when they are encapsulated. Therefore it would have been obvious to encapsulate the whitening agent when used in the chewing gums of Day et al. to improve their stability. This also meets the limitation of the stain removing components not being materially bound to the gum base.

2) Claims 9-14, 24, 25, 35 and 44-46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (WO 01/39606) in view of Cherukuri et al (4,980,178). The rejection is maintained and further applied to claims 1, 3-8, 33, 39, 42, and 43. The rejection is withdrawn in regards to claims 9-14, 24, 25 and 35.

Applicant's Arguments

Applicant argues there is no teaching or suggestion in Day of the problems associated with placing polyphosphate in the gum base, such as the base impeding the releases of the polyphosphate to perform a stain removing function. Further Day does not disclose any other stain removing agent may be incorporated into the coating. Applicant also argues the citation of Cherukuri et al. does not provide additional teaching or motivation for one of ordinary skill in the art to materially change the compositions of the primary reference to arrive at the claimed invention. This argument is not persuasive.

Examiner's Response

Although Day does not disclose the problems associated with adding polyphosphate to the gum base, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144, IV. Further, Day does teach encapsulating or adding the polyphosphate to the coating of the disclosed chewing gum. This meets the limitation of the stain removing component not being materially bound to the gum base. Day et al. further discloses whitening agents and Cherukuri et al. suggest the incorporation of active agents in a center-filled gum. Therefore it would have been obvious when formulating a center-filled gum with the active agents of Day et al. to have incorporated the actives into the center because this is suggested by Cherukuri et al.

**Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)**

1) Claims 1, 3-10, 13, 14, 25, 33, 35, 39, 40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (WO 01/39606) in view of Chaykin (US 6,013,274) further in view of Witzel et al. (US 4,238,475).

Day et al. disclose chewing gum compositions comprising poly phosphate particles. The polyphosphates include tetrapolyphosphate and hexametaphosphate, encompassing claim 3. The polyphosphate are sodium, potassium and hydrogen compounds (page 4, lines 12-35). The compounds comprise 0.1% to 50% of the compositions. Additional agents include whitening agents such as peroxides, and surfactants (page 11, lines 27-30). The gums may comprise coatings and the surface active agents may be incorporated into the coatings, encompassing claims 39 and 40 (page 11, lines 35-40). The polyphosphate is added last and may or may not be encapsulated with cellulose polymers (page 14, products A-E). The reference differs from the instant claims insofar as it does not disclose an example of a chewing gum comprising a surfactant as an active agent with the polyphosphate surface active although it is suggested, or when an anionic surfactant is used, it is not materially bound to the gum base.

Chaykin discloses oral compositions such as chewing gums (col. 1, lines 34-40) that reduce plaque and calculus deposition in the mouth improving oral cleanliness and tooth smoothness. The compositions comprise 0.01% to 20% surfactant (see Abstract).

The surfactants are an active ingredient that cleanse and sanitize (col. 2, lines 15-17). The surfactants include sodium lauryl sulfate, monoglycerides and diglycerides, monoglyceride sulfonates, fatty acid esters, fatty acids and their water-soluble salts (col. 3, lines 25-35). The type of gum is a coated gum (col. 4, lines 33-34, disclosed by incorporated reference patent 5,380,530). The reference differs from the instant claims insofar as it does not disclose the anionic surfactants are used in conjunction with polyphosphate.

It would have been obvious to one of ordinary skill in the art to have used anionic surfactants such as sodium lauryl sulfate, monoglycerides and diglycerides, monoglyceride sulfonates, fatty acid esters, fatty acids and their water-soluble salts as the surfactants in the chewing gums of Day et al. motivated by the desire to use a surfactant that reduce plaque and calculus deposition in the mouth improving oral cleanliness and tooth smoothness, as disclosed by Chaykin.

In regards to the amount of anionic surfactant, the reference discloses the amount of surfactant incorporated into the compositions ranges from 0.01% to 20%. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to use 0.1 to 2% of the surfactant in the compositions of Day et al. as supported by In re Peterson.

The combination of Day et al. and Chaykin differs from the instant claims insofar as they do not disclose the surfactants are not materially bound to the gum base.

Witzel et al. disclose chewing gum compositions capable of releasing therapeutic agents that are capable of delivering therapeutic effects to the oral cavity including the teeth. The therapeutic component is coated with gum arabic to facilitate release from the chewing gum (see Abstract). The arabic gum is a resorption retentive agent that is impervious to gum base and is not readily assimilated into gum base. The coating increases the release from the chewing gum and inhibits resorption or reabsorption of materials back into the gum bolus. The active agent is incorporated into the coated material at a ratio ranging from 4:1 to 1:1 active agent to coating (50% to 80% encompassing claim 48). The particle size ranges from about 100 mesh to 300 mesh, encompassing claim 58 (col. 3). The reference differs from the instant claims insofar as it does not disclose the active agents are peroxides, polyphosphates or anionic surfactants.

It would have been obvious to one of ordinary skill in the art to have added the anionic surfactants to the coating or encapsulated the anionic surfactants before incorporating them into the chewing gum compositions of combination of Day et al. and Chaykin motivated by the desire to facilitate their release from the chewing gum as disclosed by Witzel et al.

2) Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (WO 01/39606) in view of Chaykin (US 6,013,274) further in view of Witzel et al. (US 4,238,475) in further view of Kleber et al. (US 5,064,640).



The combination of Day et al., Chaykin and Witzel et al. is discussed above. The references differ from the instant claims insofar as they do not teach sodium stearate although they teach fatty acid and their water soluble salts.

Kleber et al. is used as general teaching disclosing sodium stearate is an anionic surfactant used in oral compositions. The reference differs from the instant claims insofar as it does not disclose the compositions of the instant claims.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to have used sodium stearate in the compositions of the combined teachings of Day et al., Chaykin and Witzel et al. motivated by the desire to use water soluble fatty acid salt disclosed to be used as an anionic surfactant in oral compositions as disclosed by Kleber et al. and supported by MPEP 2144.07.

3) Claims 1, 2, 9, 10, 13, 14, 20-22, 24, 29, 30, 33, 39, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaykin (US 6,013,274) in view of Witzel et al. (US 4,238,475) in further view of Sagel et al (6,582,708).

Chaykin and is discussed above. The reference differs from the instant claims insofar as it does not disclose the surfactants are not materially bound to the gum base.

Witzel et al. is discussed above and differs from the instant claims insofar as it does not disclose the active agents are peroxides or anionic surfactants.

It would have been obvious to one of ordinary skill in the art to have encapsulated the anionic surfactants before incorporating them into the chewing gum

compositions Chaykin motivated by the desire to facilitate their release from the chewing gum as disclosed by Witzel et al.

The combination of Chaykin and Witzel et al. differ from the instant claims insofar as they do not disclose the compositions comprise a peroxide.

Sagel has been previously discussed and differs from the instant claims insofar as it does not disclose a peroxide whitening agent in a chewing gum compositions in combination with an anionic surfactant.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to have used an encapsulated peroxide in the compositions of the combined teachings of Chaykin and Witzel et al. motivated by the desire to whiten the teeth while chewing gum, as supported by MPEP 2144.07.

## ***Unexpected Results***

### **Applicant's Unexpected Results**

Applicant's unexpected results have been previously asserted. Applicant discusses unexpected result when two stain removing agents are mixed together in the gum formulation.

### **Examiner's response**

As previously asserted, although it appears that the results are more than additive, the results are not commensurate in scope insofar as the claims recite each component generally. The results disclose the effect of sodium stearate, carbamide

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peroxide and sodium tripolyphosphate specifically as specific values whereas the claims recite anionic surfactants, peroxides and polyphosphates generally. It cannot be determined from the results disclosed by Applicant that all anionic surfactants, peroxides and polyphosphates at all concentrations will yield similar results.

Claims 1-14, 20-25, 29, 30, 33, 35, 39, 40 and 42-46 are rejected.

Claims 15-16, 18, 19, 26-28 and 36 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612